

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK  
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MSP RECOVERY CLAIMS, SERIES LLC  
et al.,

Plaintiffs,  
  
- against -

TAKEDA PHARMACEUTICALS AMERICA,  
INC. et al.,

Defendants.

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**NAOMI REICE BUCHWALD**  
**UNITED STATES DISTRICT JUDGE**

**MEMORANDUM AND ORDER**

19 Civ. 5610 (NRB)

MSP Recovery Claims, Series LLC, MSPA Claims I, LLC, and Series PMPI (collectively, "plaintiffs") move for leave to file a third amended complaint against Takeda Pharmaceuticals America, Inc., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals North America, Inc., Takeda Development Center Americas, Inc., Takeda Pharmaceuticals International, Inc., and Takeda Pharmaceutical Company Limited (collectively, "Takeda"), and Eli Lilly & Company ("Lilly," and, collectively with Takeda, "defendants"). The third amended complaint would, in pertinent part, add two claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO"). Defendants oppose plaintiffs' motion. The Court denies plaintiffs' motion for the reasons stated herein.

**BACKGROUND**

Takeda developed and defendants marketed the drug Actos,

which the FDA approved as a treatment for Type 2 diabetes in 1999. See ECF No. 92, Ex. A (Prop. Third Am. Compl. ("PTAC")) ¶¶ 60, 74. Plaintiffs allege that in the years following the FDA's approval of Actos, defendants learned from various studies that Actos increased a patient's risk of bladder cancer, but that defendants nonetheless refused to update the drug's warning label or otherwise inform the public. See, e.g., PTAC ¶¶ 101-11. Plaintiffs also allege that Takeda misled the FDA into believing that the studies showing that Actos increased a patient's risk of bladder cancer were erroneous, see, e.g., PTAC ¶ 88, and that defendants marketed Actos in a manner designed to conceal that increased risk, see, e.g., PTAC ¶ 132.

On September 17, 2010, after additional studies demonstrated that Actos increased a patient's risk of bladder cancer, the FDA announced that it would conduct a safety review of Actos. PTAC ¶ 123. On June 15, 2011, the FDA announced that "use of . . . Actos . . . for more than one year may be associated with an increased risk of bladder cancer," and that "[i]nformation about this risk will be added to the Warnings and Precautions section of the label" for all drugs that included Actos's active ingredient. PTAC ¶ 130. Defendants accordingly changed Actos's warning label to warn of bladder cancer, after which the drug's sales decreased

by an alleged 80%. PTAC ¶¶ 131, 134.

Following the FDA's announcement, patients and families of patients who had been prescribed Actos and who had developed bladder cancer after ingesting the drug filed thousands of personal injury and wrongful death lawsuits in federal and state courts across the United States. See PTAC ¶¶ 155-56. The federal cases were consolidated into a multidistrict litigation in the Western District of Louisiana. PTAC ¶¶ 154. The first and only bellwether trial lasted nearly 40 days and returned a jury verdict in favor of the plaintiffs. See In re Actos (Pioglitazone) Prods. Liab. Litig., No. 12 Civ. 64 (RFD), 2014 WL 4286927, at \*1 (W.D. La. Aug. 28, 2014). Thereafter, defendants entered a global settlement program for all eligible personal injury claimants who had used Actos before December 1, 2011 and who had been diagnosed with bladder cancer. In re Actos (Pioglitazone) Prods. Liab. Litig., 274 F.Supp. 3d 485, 503 (W.D. La. 2017).

Plaintiffs are three entities to which 56 organizations that administer Medicare Parts C and D benefits for Medicare beneficiaries have assigned their legal rights to recover payments made for Actos prescriptions. See PTAC ¶ 33. Plaintiffs allege that their assignors paid all or part of the cost of Actos prescribed to and ingested by their enrollees. PTAC ¶ 36.

Plaintiffs' assignors are third-party payors ("TPPs"). PTAC ¶ 195. TPPs reimburse the health care expenses, including the prescription drug costs, of their members. The canonical example of a TPP is a health benefit plan, which pays the balance of its members' prescription drug costs after copays. Most TPPs, including plaintiffs' assignors, contract out their prescription drug coverage to pharmacy benefit managers ("PBMs"), which are companies that manage outpatient drug claims. See PTAC ¶ 195. PBMs use formularies, or lists of approved medications, to determine whether a plan covers a drug and, if so, what coverage the drug receives. A PBM includes a drug on its formulary only if its Pharmacy and Therapeutics Committee, which is comprised of physicians and clinical pharmacists, decides that it should do so after reviewing the drug's publicly available clinical information. Generally, TPPs reimburse the cost of a prescription drug only if the drug is on the formulary of the PBM with whom the TPP has contracted. Neither TPPs nor PBMs, however, have a role in the therapeutic decision of whether to prescribe a prescription drug to a patient, and, if so, which drug to prescribe. That decision is entrusted solely to physicians, who consider a range of factors, including factors specific to the patient and factors based on the physician's experience with, and knowledge of,

applicable treatment options, including available prescription medications.

Plaintiffs filed the present action on June 14, 2019. See ECF No. 1 (Compl.). Their initial complaint asserted more than 30 claims under the laws of 23 states and Puerto Rico. Compl. ¶¶ 230-474. It also asserted two civil RICO claims under 18 U.S.C. § 1964 on the ground that defendants had committed thousands of instances of mail and wire fraud in violation of 18 U.S.C. §§ 1341 and 1343 by intentionally concealing that Actos increased a patient's risk of bladder cancer. See Compl. ¶¶ 200-229. Plaintiffs based their RICO claims on what is referred to as the "quantity effect" theory of injury, which posits that plaintiffs' assignors paid for more prescriptions of Actos than they would have absent defendants' allegedly fraudulent promotion of the drug. See, e.g., Compl. ¶ 18.<sup>1</sup>

On July 16, 2019, for reasons undisclosed to the Court, plaintiffs amended their initial complaint to withdraw both of their RICO claims. See ECF No. 4. After defendants filed a pre-motion letter regarding a contemplated motion to dismiss the amended complaint, the Court granted plaintiffs leave to amend

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<sup>1</sup> Plaintiffs do not assert what is referred to as the "excess price" theory of injury, which posits that plaintiffs' assignors' paid more for Actos prescriptions than they would have absent defendants' allegedly fraudulent promotion of the drug.

their amended complaint. See ECF No. 45. Plaintiffs filed a second amended complaint on September 23, 2019. See ECF No. 46.

On December 3, 2019, the U.S. Court of Appeals for the Ninth Circuit issued a decision that, according to plaintiffs, supported the viability of the RICO claims that they had relinquished. Specifically, in Painters & Allied Trades Dist. Council 82 Health Care Fund v. Takeda Pharm. Co. Ltd., 943 F.3d 1243 (9th Cir. 2019) ("Painters"), a putative class action against the same defendants sued here and based on essentially the same allegations as the present case, the Ninth Circuit reversed the district court's February 1, 2018 decision dismissing the plaintiffs' RICO claims under Federal Rule of Civil Procedure 12(b)(6) for failing to allege that defendants' misleading promotion of Actos proximately caused the plaintiffs' injuries under the quantity effect theory of injury. Apparently rethinking their strategic decision to abandon their RICO claims, plaintiffs moved for leave to reassert them in a third amended complaint.

#### **DISCUSSION**

Plaintiffs move for leave to amend their second amended complaint as set forth in the proposed third amended complaint, which, in pertinent part, asserts two claims against defendants under § 1964(c) of RICO. See PTAC ¶¶ 207-236.

Plaintiffs move for leave to amend under Federal Rule of Civil Procedure 15(a)(2), which provides that “[t]he court should freely grant leave [to amend] when justice so requires.” Fed. R. Civ. P. 15(a)(2). Rule 15(a)(2)’s mandate that leave should be “freely grant[ed]” embodies a “strong preference for resolving disputes on the merits.” Williams v. Citigroup Inc., 659 F.3d 208, 212-13 (2d Cir. 2011) (internal quotation marks omitted). Accordingly, leave to amend is properly denied only in certain circumstances, one of which is when the proposed amendments are futile. Monahan v. N.Y.C. Dept. of Corrections, 214 F.3d 275, 283 (2d Cir. 2000) (citing Foman v. Davis, 371 U.S. 178, 182 (1962)).

Proposed amendments are futile if they would fail to withstand a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6). Panther Partners Inc. v. Ikanos Commc’ns., Inc., 681 F.3d 114, 119 (2d Cir. 2012). Under Rule 12(b)(6), “a complaint must contain sufficient factual matter, accepted as true, to ‘state a claim for relief that is plausible on its face.’” Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009) (quoting Bell Atl. Corp. v. Twombly, 550 U.S. 544, 570 (2007)). “A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged.” Id.

Under § 1964(c) of RICO, a plaintiff must allege "(1) a substantive RICO violation under § 1962; (2) injury to the plaintiff's 'business or property,' and (3) that such injury was 'by reason of' the substantive RICO violation." City of New York v. Smokes-Spirits.com, Inc., 541 F.3d 425, 439 (2d Cir. 2008), rev'd on other grounds sub nom. Hemi Group, LLC v. City of New York, 559 U.S. 1 (2010) ("Hemi Group") (quoting 18 U.S.C. § 1964(c)). Among other things, defendants contend that plaintiffs' RICO claims are futile because their assignors' asserted injuries under the quantity effect theory -- i.e., paying for more Actos prescriptions than they would have absent defendants' allegedly fraudulent promotion of the drug -- fail to meet § 1964(c)'s "by reason of" requirement. Because the Court agrees with this contention, it declines to consider the balance of defendants' arguments against granting plaintiffs leave to amend and denies plaintiffs' motion.

**a. RICO's "By Reason Of" Requirement**

The phrase "by reason of" in § 1964(c) requires that the defendant's alleged RICO violations were but-for and proximate causes of the plaintiff's injuries. Sergeants Benevolent Ass'n Health & Welfare Fund v. Sanofi-Aventis U.S. LLP, 806 F.3d 71, 86-87 (2d Cir. 2015) ("Sergeants") (citing Holmes v. Sec. Inv'r Prot.



Corp., 503 U.S. 258, 268 (1992) ("Holmes"). Proximate cause for purposes of RICO, however, does not precisely trace common-law notions of proximate cause. See Bridge v. Phoenix Bond & Indem. Co., 553 U.S. 639, 654-55 (2008). The requirements for proximate cause under RICO are instead "stricter than those for common-law torts." Empire Merchants, LLC v. Reliable Churchill LLLP, 902 F.3d 132, 145 (2d Cir. 2018) ("Empire Merchants") (internal quotation marks omitted). Specifically, the Supreme Court has "made clear" that "for RICO purposes," proximate cause "requires 'some direct relation between the injury asserted and the injurious conduct alleged.'" Hemi Group, 559 U.S. at 9 (quoting Holmes, 503 U.S. at 268). Under this "directness requirement," Anza v. Ideal Steel Supply Corp., 547 U.S. 451, 458 (2006) ("Anza"), "[a] link that is 'too remote,' 'purely contingent,' or 'indirect' is insufficient," Hemi Group, 559 U.S. at 9 (quoting Holmes, 503 U.S. at 271, 274).

The Second Circuit has previously considered whether, for purposes of RICO, a drug manufacturer's fraudulent promotion of a drug proximately causes TPPs to suffer harm under the quantity effect theory of injury. In UFCW Local 1776 v. Eli Lilly & Co. ("Zyprexa"), patients and TPPs brought a putative class action against Lilly on the ground that it had misrepresented the side

effects of the drug Zyprexa to physicians and had promoted Zyprexa for off-label uses -- uses for which the FDA had not approved the drug -- absent evidence that Zyprexa was effective for those uses. 620 F.3d 121, 123, 129 (2d Cir. 2010). Relying on both the quantity effect and excess price theories of injury, the plaintiffs moved to certify a class of TPPs, which, under Federal Rule of Civil Procedure 23(b)(3), required them to be able to prove each element of their RICO claims, including causation, using generalized proof. Id. at 130-31. Lilly, meanwhile, moved for summary judgment. Id. at 130. The district court denied Lilly's motion for summary judgment, and certified a class of TPPs under the excess price theory. Id.

The Second Circuit reversed the district court's certification of a class of TPPs. With respect to the quantity effect theory in particular, the Second Circuit concluded that "[t]he nature of prescriptions . . . means that this theory of causation is interrupted by the independent actions of prescribing physicians, which thwarts any attempt to show proximate cause through generalized proof." Id. at 135. Specifically, while the plaintiffs had argued that "the ultimate source for the information on which doctors based their prescribing decisions was Lilly and its consistent, pervasive marketing plan," the Second Circuit

noted that "Lilly was not, however, the only source of information on which doctors based prescribing decisions." Id. (emphasis in original). Instead, "[a]n individual patient's diagnosis, past and current medications being taken by the patient, the physician's own experience with prescribing Zyprexa, and the physician's knowledge regarding the side effects of Zyprexa [were] all considerations that would have been taken into account in addition to the alleged misrepresentations distributed by Lilly." Id. (emphasis in original). Accordingly, because "individual physicians prescribing Zyprexa may have relied on Lilly's misrepresentations to different degrees, or not at all," the causal chain was severed. Id. at 136.

The Second Circuit refrained, however, from extending its class certification holding regarding the quantity effect theory also to decide Lilly's motion for summary judgment, noting that "while that theory cannot support class certification, it is not clear that the theory is not viable with respect to individual claims by some TPPs or other purchasers." Id. at 136. Because the district court had not considered individual claims under the quantity effect theory when it adjudicated Lilly's motion for summary judgment, though, the Second Circuit "decline[d] to consider whether summary judgment with respect to the quantity

effect theory is appropriate in the first instance.” Id.

The Second Circuit applied Zyprexa’s holding five years later in Sergeants, a putative class action in which TPPs, relying on the quantity effect theory of injury, asserted RICO claims against Sanofi-Aventis for its alleged failure to disclose the risks of its antibiotic Ketek. See 806 F.3d at 74. The district court had denied class certification on the ground that Zyprexa foreclosed the plaintiffs from using generalized proof to establish causation, and had granted summary judgment in favor of Sanofi-Aventis because the plaintiffs had failed to adduce individualized evidence of causation. Id. at 74-75. The Second Circuit affirmed the denial of class certification, stating that “Zyprexa control[led],” id. at 97, and noting, among other things, “the multitude of factors recognized in Zyprexa as entering into individual physicians’ prescribing decisions,” id. at 92.<sup>2</sup>

It also affirmed the district court’s decision to grant summary judgment to Sanofi-Aventis. See id. at 97-98. In so doing, the Second Circuit “reaffirmed” the “distinction drawn in Zyprexa” that “a plaintiff is not necessarily foreclosed from bringing a RICO claim merely because its attempt to certify a class

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<sup>2</sup> It appears that the structure of plaintiffs, namely, as assignees of 56 TPPs’ legal rights to recover for payments made for Actos prescriptions, is specifically designed to circumvent Second Circuit law, which clearly precludes litigating a case under the quantity effect theory as a class action.

using generalized proof has failed.” Id. at 97. The Second Circuit instead hypothesized that “it may be possible for a plaintiff to establish its own claim . . . using aggregate statistical proof -- i.e., without having to show the individual reliance of thousands of prescribing doctors . . . .” Id. The Second Circuit declined to explore the possibility, however, because the plaintiffs had adduced no such evidence. See id. at 97-98. Moreover, it refused to “express any view on what evidence [p]laintiffs might have presented in order to succeed on their individual claims . . . .” Id. at 98 n.11.

#### **b. Analysis**

While the Second Circuit has refrained from deciding whether the quantity effect theory is viable with respect to individual claims by TPPs, the reasoning on which Zyprexa based its class certification holding compels the conclusion that it is not. The Second Circuit held in Zyprexa that TPPs could not use generalized proof to establish proximate cause under the quantity effect theory because “the nature of prescriptions . . . means that this theory of causation is interrupted by the independent actions of prescribing physicians.” 620 F.3d at 135. Specifically, because a physician considers a multitude of inputs apart from manufacturer-provided information when deciding whether to

prescribe a drug to a patient, the physician's decision is sufficiently independent to sever the causal chain from the drug manufacturer to the TPP. See id. Because that severance results from the "nature" of prescriptions generally, it applies with equal force to other prescription drugs, including Actos. The Seventh and Ninth Circuits have accordingly recognized Zyprexa as standing for the general proposition that, under RICO, a drug manufacturer's fraudulent promotion of a drug does not proximately cause TPPs' injuries. See Sidney Hillman Health Ctr. of Rochester v. Abbott Labs., 873 F.3d 574, 578 (7th Cir. 2017) ("Sidney Hillman") ("[Sergeants], and [Zyprexa], hold that there are so many layers, and so many independent decisions, between promotion and payment that the causal chain is too long" for TPPs to "recover under RICO for wrongs committed while marketing pharmaceuticals. . . . [T]he Second Circuit has this right."); Painters, 943 F.3d at 1257 (describing Zyprexa as having held "that prescribing physicians' . . . decisions constitute an intervening cause to sever the chain of proximate cause"). Under Zyprexa, then, the independent decisionmaking of prescribing physicians severs the causal chain from defendants to plaintiffs' assignors, thus rendering plaintiffs' assignors' injuries under the quantity effect theory too attenuated to meet RICO's proximate cause requirement.

Plaintiffs resist this conclusion on various grounds. As an initial stratagem, they try to reframe Sergeants as having held that, under RICO, individual TPPs can show that a drug manufacturer's fraudulent promotion of a drug proximately caused their injuries under the quantity effect theory. They base this recasting on the fact that Sergeants noted in its summary judgment discussion that "it may be possible for a plaintiff to establish its own claim (as opposed to the claims of each class member) using aggregate statistical proof." 806 F.3d at 97.<sup>3</sup> Sergeants, however, did not comment further on that possibility. See id. Rather, it declined to "express any view on what evidence [p]laintiffs might have presented in order to succeed on their individuals claims, as [p]laintiffs neither assert that they have put forth such proof nor challenge the district court's conclusion that they have not done so." Id. at 98 n.11 (emphases added). Sergeants therefore did not hold that individual TPPs could use

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<sup>3</sup> Plaintiffs also claim that Sergeants cited approvingly to the statistical evidence that the plaintiffs had offered in In re Neurontin Marketing & Sales Practicing Litigation, 712 F.3d 21 (1st Cir. 2013) ("Neurontin"), in which the First Circuit held that individual TPPs had adduced sufficient evidence to support a jury's finding that Pfizer's misleading promotion of a drug had caused their injuries under RICO. Not so. Rather, in its class certification discussion, Sergeants "distinguish[ed]" Neurontin, stating that it "need not (and d[id] not intend to) express any view here on whether or when an aggregate regression analysis similar to the one deployed in Neurontin might be sufficient to prove causation on a class-wide basis in other pharmaceutical-marketing cases," and affirmed the district court's denial of class certification, declaring that "Zyprexa control[led]." Sergeants, 806 F.3d at 97.

statistical evidence to establish proximate cause, and plaintiffs' contrary contention falls flat.<sup>4</sup>

Unable to transform the holding of Sergeants, plaintiffs change gears and ask the Court to discard Zyprexa in favor of the Ninth Circuit's decision in Painters. But Painters, which plaintiffs concede was their impetus for moving for leave to reassert their abandoned RICO claims, expressly acknowledged not only that the courts of appeals were split over "whether the decisions of prescribing physicians and pharmacy benefit managers constitute intervening causes that sever the chain of proximate cause between the drug manufacturer and TPP," but also that it was taking the side "opposite" to the Second Circuit in that split.

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<sup>4</sup> Plaintiffs also highlight how Sergeants noted that "it [was] possible . . . to envision a drug so dangerous that no physician would ever prescribe it to treat a non-fatal condition if that physician were aware of its true risks. And, in such an extraordinary case, a reasonable jury might well be able to infer solely from a precipitous drop-off in sales that any prescription for the drug was necessarily written in reliance on the defendant's concealment of the drug's risks." Sergeants, 806 F.3d at 92. According to plaintiffs, Actos is such a drug. Their own evidence, however, refutes that assertion, as a nonexhaustive list of instances in which their assignors paid for Actos prescriptions, which plaintiffs submitted with their proposed third amended complaint, lists hundreds, if not thousands, of instances in which plaintiffs' assignors paid for Actos prescriptions after the FDA's June 15, 2011 announcement that Actos's warning label must warn that Actos increases a patient's risk of bladder cancer. See PTAC, Ex. D.



See 943 F.3d at 1257.<sup>5</sup> Indeed, to conclude that the prescribing decisions of physicians do not sever the chain of causation under the quantity effect theory, as the Ninth Circuit concluded in Painters, is to reject the contention at the heart of Zyprexa's analysis of proximate cause under that theory. Painters is accordingly diametrically contrary to Zyprexa and, as such, cannot be reconciled with it.

Failing to appreciate that decisions of the Second Circuit bind the district courts in it, plaintiffs rehash certain arguments that the Ninth Circuit made in Painters. For example, the Ninth Circuit reasoned in Painters that "because of the structure of the American health care system," defendants always knew that "physicians would not be the ones paying for the drugs they prescribed," and that "TPPs and individual patients [would instead] pay for the drugs." Id. at 1257 (internal quotation marks omitted). Thus, because "the alleged fraudulent marketing scheme . . . only became successful once they received payments for the

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<sup>5</sup> Presently, in the Second and Seventh Circuits, TPPs' injuries are too attenuated to recover under RICO for a drug manufacturer's fraudulent promotion of a drug. See Zyprexa, 620 F.3d at 135-36; Sidney Hillman, 873 F.3d at 578. The First, Third, and Ninth Circuits, by contrast, have reached the opposite conclusion. See Neurontin, 712 F.3d at 38-39; In re Avandia Mktg., Sales Practices & Prod. Liab. Litig., 804 F.3d 633, 634 (3d Cir. 2005); Painters, 943 F.3d at 1259. As the Ninth Circuit explained, "the central dispute between the Second and Seventh Circuits and the First and Third Circuits is whether the decisions of prescribing physicians and pharmacy benefit managers constitute intervening causes that sever the chain of proximate cause between the drug manufacturer and TPP." Painters, 943 F.3d at 1257 (footnote omitted).

additional Actos prescriptions they induced," it was "perfectly foreseeable that physicians who prescribed Actos would play a causative role in" that scheme. Id. (internal quotation marks and alterations omitted). Plaintiffs contend that this argument demonstrates that defendants' alleged fraud proximately caused their assignors to pay for too many Actos prescriptions.

That argument, however, suffers from a fatal shortcoming: "foreseeability and intention have little to no import for RICO's proximate cause test." Empire Merchants, 902 F.3d at 145 (citing Hemi Group, 559 U.S. at 12). As the Supreme Court has explained, "[t]he concepts of direct relationship and foreseeability are of course two of the 'many shapes proximate cause took at common law.' Our precedents make clear that in the RICO context, the focus is on the directness of the relationship between the conduct and the harm. Indeed, Anza and Holmes never even mention the concept of foreseeability." Hemi Group, 559 U.S. at 12 (internal alteration and citation omitted) (quoting Holmes, 503 U.S. at 268). Whether plaintiffs' assignors were foreseeable victims, or even the intended targets, of defendants' alleged fraud is consequently irrelevant to whether that fraud proximately caused their assignors' injuries under RICO. Id.

Finally, plaintiffs attempt to distinguish Zyprexa on the

ground that unlike Lilly's fraudulent promotion of Zyprexa, which had focused on Zyprexa's off-label uses, defendants fraudulently promoted Actos for its FDA-approved use -- the treatment of Type 2 diabetes. This distinction is unavailing. As Zyprexa observed, a drug manufacturer's fraudulent promotion of a prescription drug is not the only source of information upon which prescribing physicians base their decisions to prescribe it. 620 F.3d at 135. Rather, physicians consider a multitude of factors apart from information from the drug manufacturer. Id. Because those factors are unrelated to the manufacturer's marketing, and because the consideration of those factors is what, according to Zyprexa, interrupts the quantity effect theory's chain of causation, whether a drug manufacturer's fraudulent promotion concerns approved indications or off-label uses is inapposite. See id.

The Court accordingly finds that, under Zyprexa and Sergeants, plaintiffs have failed to allege that their assignors' injuries under the quantity effect theory were "by reason of" defendants' alleged RICO violations. Plaintiffs' RICO claims are thus futile, and, as such, the Court denies plaintiffs leave to


amend to reassert them in a third amended complaint.<sup>6</sup>

**CONCLUSION**

The Court denies plaintiffs' motion for leave to amend for the reasons stated herein. The Clerk of Court is respectfully directed to terminate the motion pending at ECF No. 92.

**SO ORDERED.**

Dated: New York, New York  
August 6, 2020

  
NAOMI REICE BUCHWALD  
UNITED STATES DISTRICT JUDGE

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<sup>6</sup> The Court rejects defendants' argument that plaintiffs lack Article III standing for failure to allege an injury in fact. The quantity effect theory of injury posits a financial injury to a TPP -- paying for prescriptions that physicians would not have written absent the drug manufacturer's fraud -- that exists regardless of whether the drug ultimately injures any of the TPP's members. Cf. Desiano v. Warner-Lambert Co., 326 F.3d 339, 349 (2d Cir. 2003) (explaining that under the excess price theory of injury, TPPs suffer "an injury . . . that is unaffected by whether any given patient who ingested Rezulin became ill."). Plaintiffs therefore need not allege that their assignors' enrollees developed bladder cancer or another ailment from Actos, and the cases on which defendants rely, each of which concerned a patient's standing to bring personal injury claims against a drug manufacturer for misleadingly promoting a drug that the patient ingested without harm, are inapposite.